IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al*., Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*., Defendants.	CIV. NO. TDC-20-1320

PLAINTIFFS' MOTION FOR CLARIFICATION

I. INTRODUCTION

On July 13, this Court granted in part Plaintiffs' Motion for Preliminary Injunction, finding that "an in-person visit to pick up medication and sign forms [is] particularly burdensome and dangerous during the pandemic" and affording patients a "temporary option to forgo in-person visits if, in a healthcare provider's medical judgment, it is not necessary to meet the patient's needs." Mem. Op. ("PI Opinion"), ECF No. 90, 49, 57. Specifically, the Court barred Defendants from enforcing the requirement "that mifepristone may be dispensed only in clinics, medical offices, or hospitals, rather than by mail or delivery service," while specifying that such "[d]ispensing by mail or delivery service must still occur by or under the supervision of a certified healthcare provider as defined in the REMS." Prelim. Inj. ("the Injunction"), ECF No. 92, ¶ (1)(a).

Plaintiffs now seek confirmation that, under the Injunction, clinicians may dispense mifepristone through a supervised delivery service agreement with one of a very limited number of mail-order pharmacies (likely one or two) that will contract to stock the medication and deliver it directly to patients only at the direction and under the supervision of a clinician prescribing mifepristone pursuant to a REMS certification agreement. Plaintiffs seek this clarification because there is a potential discrepancy between the Injunction (which permits this delivery model) and three phrases in the Court's Opinion (which seemingly would not).

Although Defendants have filed a notice of appeal, this Court retains jurisdiction to clarify a "discrepancy [that] could cause confusion" regarding the scope of the injunction, because doing so would "aid[] the appellate process" by "eliminat[ing] issues . . . 'begotten merely from imprecise wording' in the appealed order." *Amaya v. DGS Constr., LLC*, No. TDC-16-3350, 2019 WL 1501584, at *2 (D. Md. Jan. 28, 2019) (Chuang, J.) (quoting *Lytle v. Griffith*, 240 F.3d 404, 407 n.2 (4th Cir. 2001)). And there is an urgent need for such clarification in order to afford relief to

those patients who are experiencing the constitutional injury, medical risk, and other burdens on which the Injunction is based, but whose prescribers are unable to direct and supervise the delivery of mifepristone *from their health care facility*, rather than pursuant to a pre-arranged, supervised delivery agreement with a designated mail-order pharmacy company that can deliver mifepristone to their patients and report back to the prescriber the medication package serial number and shipping tracking information.

II. BACKGROUND

A. Preexisting REMS Framework

Under 21 U.S.C. § 355-1(f)(3), the FDA has authority to impose six types of elements to assure safe use ("ETASU") as part of a REMS program, as long as certain conditions are met. *See* Pls.' Mem. Supp. Mot. Prelim. Inj. ("Pls.' PI Mem."), ECF No. 12, 7-9. Under its ETASU A authority, 21 U.S.C. § 355-1(f)(3)(A), the FDA may require that "health care providers who prescribe [a] drug . . . are specially certified"; under its ETASU C authority, *id.* § 355-1(f)(3)(C), the FDA may require "that [a] drug be dispensed to patients only in certain health care settings, such as hospitals"; and pursuant to its ETASU D authority, *id.* § 355-1(f)(3)(D), the FDA may require that "the drug be dispensed to patients with . . . documentation of safe-use conditions . . . ." The statute also authorizes the FDA to impose an "[i]mplementation system" for any ETASU. *Id.* § 355-1(f)(4). The REMS statute nowhere separately authorizes or discusses restrictions on drug distribution. *See generally id.*

The REMS for mifepristone consists of: a goal; requirements pursuant to ETASU A, C, and D; an implementation system; and a timetable for the drug sponsors to submit periodic assessments to the FDA. Compl. Ex. 2 ("Mifepristone REMS"), ECF No. 1-4. The stated goal is:

> [T]o mitigate the risk of serious complications associated with mifepristone by:

> a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.
> b) Ensuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber.
> c) Informing patients about the risk of serious complications associated with mifepristone.

Id. (I)(a)-(c). Consistent with section (b) of this goal, the FDA requires that "[m]ifepristone must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber." *Id.* (II)(A)(2).

In service of this restriction, the Mifepristone REMS requires the drug sponsors to: "(i) [e]nsure that their mifepristone is available to be dispensed to patients only in clinics, medical offices and hospitals by or under the supervision of a certified prescriber," and "(ii) [e]nsure that their mifepristone is not distributed to or dispensed through retail pharmacies or other settings not described above." *Id.* (II)(A)(2)(a)(i)-(ii). The "Implementation System" section of the Mifepristone REMS contains further instructions for the mifepristone drug sponsors and the "distributors who distribute their mifepristone" to effectuate the ETASU requirements. *Id.* (II)(B).

B. The Injunction

On July 13, this Court enjoined Defendants and their agents from enforcement of "the following provisions of the 'Elements to Assure Safe Use' . . . set forth in the mifepristone [REMS] . . . as to the dispensing of mifepristone for use as part of a medication abortion regimen, against Plaintiffs, their members, other similarly situated individuals or entities, and other individuals or entities involved in implementing the injunctive relief." Injunction ¶ (1).

Referring to the three categories of ETASU (rather than any particular text in the Mifepristone REMS document), this Court enjoined, *inter alia*:

> ETASU C, 21 U.S.C. § 355-1(f)(3)(C), only to the extent that it requires that mifepristone may be dispensed only in clinics, medical offices, or hospitals, rather than by mail or delivery service.

> Dispensing by mail or delivery service must still occur by or under the supervision of a certified healthcare provider as defined in the REMS.

Id. ¶ (1)(a). The Injunction thus limits—but does not eliminate—the dispensing restrictions for mifepristone. During the relevant time period, *see id.* ¶ (2), dispensing may occur only in person at a hospital, clinic, or medical office, or by mail or delivery service; it may *not* occur in person at any other type of physical setting, including a retail pharmacy.[1] And, a clinician may not issue a mifepristone prescription to their patient to fill through the pharmacy of their choice (even if using mail or delivery): dispensing by mail or delivery must be *directed and supervised by* a clinician prescribing mifepristone pursuant to a REMS certification agreement.

The Injunction does not, and need not, separately discuss the language at (II)(A)(2)(a)(i) of the Mifepristone REMS limiting where mifepristone may be <u>distributed</u> for dispensing: this requirement tracks and implements the ETASU C dispensing restriction but is not (and cannot be) independently authorized under the REMS statute.[2] *See supra* at 3. The scope of the distribution

[1] "Retail" and "mail-order" pharmacies are distinct entities. *See, e.g.*, Defs.' Mem. Opp'n Pls.' Mot. Prelim. Inj. ("Defs.' PI Opp'n"), ECF No. 62, 6 ("retail or mail-order pharmacies"), 22 (same); Office of Inspector General, U.S. Dep't of Health & Human Servs., Retail Pharmacies with Questionable Part D Billing 2 (2012), https://oig.hhs.gov/oei/reports/oei-02-09-00600.pdf ("Pharmacies include retail, long-term-care, and mail-order; they may be independently owned or part of a chain."); U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy for Qysmia®*, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Qysmia_2017-07-03_REMS_full.pdf (last visited July 25, 2020) (separately regulating "each pharmacy chain, each independent retail pharmacy, and each mail order pharmacy"); 21 C.F.R § 209.2 (2020) (FDA regulation recognizing a variety of different pharmacy models, such as "retail, mail order, Internet, hospital, university, or clinic pharmac[ies]"). As Defendants acknowledge, retail pharmacies are generally understood to be physical stores. *See* Defs.' PI Opp'n 21 n.3 ("Retail pharmacies are also likely in many instances to be riskier locations to pick up Mifeprex than a clinic or doctor's office, given higher foot traffic and a lower likelihood of enforcing social distancing and face-mask requirements than clinical settings.").

[2] Plaintiffs' challenge to ETASU C and express request for relief allowing dispensing through "retail or mail-order" pharmacies necessarily encompassed a challenge to language in the REMS implementing those requirements, including by restricting distribution. *See* Pls.' Reply Br. Supp.

restriction thus parallels the scope of the dispensing restriction, which the Injunction has now temporarily narrowed. Since neither the REMS nor the Injunction authorizes dispensing at retail pharmacies, the mifepristone manufacturers may not distribute to retail pharmacies. But where the Injunction permits "[d]ispensing by mail or delivery service . . . by or under the supervision of a certified" prescriber, the manufacturers may distribute mifepristone to a mail-order pharmacy that will deliver the medication to patients only under the supervision of a certified prescriber. Injunction ¶ (1)(a). This is also consistent with the Injunction's protection for "other individuals or entities involved in implementing the injunctive relief," *id.* ¶ (1), which Plaintiffs requested for precisely this purpose, *see* Pls.' PI Mem. 35 (requesting relief for "any other individuals involved in implementing this Court's relief (such as the drug manufacturer or a mail-order pharmacy).").

C. Supervised Mail-Order Delivery Model

Under the model Plaintiffs and their members seek to utilize, the drug manufacturer would contract, in advance, with a very limited number of mail-order pharmacies to stock the mifepristone and serve as a designated delivery service for patients, delivering the medication only at the direction and under the supervision of prescribers acting pursuant to a REMS certification agreement. Individual prescribers would then enter into a supervised delivery agreement with the mail-order company, under which the prescriber confirms that they are prescribing pursuant to a REMS certification agreement, and the mail-order company agrees to deliver the mifepristone at the direction and under the supervision of that prescriber, including reporting back to the prescriber the package serial number and shipping tracking information. Consistent with this Court's order, the prescriber would use this delivery method during the Public Health Emergency only where

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Mot. Prelim. Inj. ("Pls.' PI Reply"), ECF No. 73, 15 n.13 (citing examples from Complaint and briefing).

medically appropriate and "the most efficient means" of delivering the mifepristone to a particular medication abortion patient.[3] PI Opinion 58.

This model not only is consistent with the Injunction, but also is very similar to that approved by the FDA for Korlym®, the mifepristone product used as treatment for Cushing's Syndrome. The FDA declined to impose a REMS for Korlym in part due to the manufacturer's decision to distribute the medication "solely to a 'limited number of specialty pharmacies,'" permitting "[p]hysicians [to] submit their prescriptions through this central pharmacy to have Korlym delivered directly to the patient." Defs.' PI Opp'n, Ex. 24 ("Korlym Summary Review"), ECF No. 62-16, 0328; U.S. Food & Drug Admin., *Medical Review(s)* (Jan. 13, 2012) ("Korlym Medical Review") 14, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000MedR.pdf.

D. Confusion Regarding Language in the PI Opinion

Although the Injunction itself would permit prescribers acting pursuant to a REMS certification agreement to work with a designated mail-order pharmacy for the purpose of supervised delivery of mifepristone, three phrases in the PI Opinion are causing confusion in implementing the Injunction and limiting Plaintiffs' and their members' patients' relief:

> [W]here the REMS require that **the drug sponsor distribute mifepristone only to certified healthcare providers and not to retail pharmacies,** . . . a temporary waiver of the In-Person Requirements would not open up the distribution chain in a way that takes control away from those healthcare providers. Rather, such healthcare providers would be able to choose the most efficient means of **getting the drug from their office to their patient** under the existing circumstances, whether by mail, courier, or in-person . . . .

[3] The Public Health Emergency has been extended and is currently scheduled to remain in place through, at a minimum, October 23, 2020. U.S. Dep't of Health & Human Servs., *Renewal of Determination That a Public Health Emergency Exists* (July 23, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx.

> [D]ispensing . . . must still be conducted "by or under the supervision of a certified prescriber," and the drug sponsor must still ensure that mifepristone is not "**distributed to or dispensed through retail pharmacies," so the drug will still have to be distributed first to certified healthcare providers** who then must arrange for the mailing or delivery of the mifepristone to their patients and must still arrange to record the serial numbers of the distributed packages of mifepristone.

PI Opinion 58-59, 79-80 (emphasis added). It is clear that mifepristone dispensing may not occur at retail pharmacies, and thus the medication cannot be distributed to those settings. But neither of these passages discusses a scenario in which the drug sponsor contracts, in advance, with a very limited number of mail-order pharmacies that deliver the medication to patients only at the direction and under the supervision of prescribers acting pursuant to a REMS certification agreement, including providing the package serial number and tracking information to the prescriber. This model aligns with both the purpose of the Injunction—to mitigate the harm of a "rigid In-Person Dispensing Requirement" during the pandemic by affording clinicians a "temporary option" to mail or deliver mifepristone to their patients where medically appropriate, *id.* at 57-58; *see also id.* at 79-80—as well as its limits, ensuring that such mail or delivery dispensing still occurs under the supervision of a certified REMS prescriber, Injunction ¶ (1)(a).

III. ARGUMENT

A. There Is an Urgent Need for Clarification.

"[T]he language of the [Injunction] is controlling, because courts speak through their orders" rather than their opinions. *Dixon v. Edwards*, 290 F.3d 699, 720 (4th Cir. 2002) (citing *New Horizon of N.Y. LLC v. Jacobs,* 231 F.3d 143, 152 (4th Cir. 2000)). The Injunction permits the supervised delivery model Plaintiffs describe above. However, the three phrases in the PI Opinion that assume that mifepristone will be distributed only to clinicians' offices are creating

significant confusion as to whether the drug sponsor and clinicians will face penalties if they proceed with this delivery model pursuant to the Injunction. Defendants' stated opposition to this motion underscores the need for clarity. *See* PI Opinion 3, 20-21 (discussing REMS penalties).

If *all* deliveries of mifepristone must originate from a certified prescriber's office and cannot originate from a designated mail-order pharmacy acting under the prescriber's supervision, some medication abortion patients will continue to be forced to undertake needless travel and risk during this pandemic as a result of the REMS. For instance, as Plaintiffs' evidence demonstrated and as this Court found, "during the pandemic, medical offices that dispense mifepristone may be closed," *id.* at 61, and such closures are increasingly likely given the national resurgence of COVID-19, *id.* at 46 ("[O]ffices that have reopened may close for a second time"). Thus, without the option to supervise delivery through a mail-order pharmacy, clinicians whose offices are closed may have to turn away their patients needing medication abortion care.

In addition, some clinicians face barriers due to general state regulations that limit the circumstances under which clinicians, as opposed to pharmacies, may directly mail any prescription medication—a regulatory landscape that assumes a pharmacy option, as exists for all but 17 drugs out of 20,000.[4] *See* PI Opinion 5; Pls.' PI Reply 14. In short, absent this clarification, patients and clinicians will continue to needlessly suffer the very risks necessitating the Injunction.

B. This Model Does Not Raise Any Concerns Identified by the FDA.

The Court's emphasis on ensuring that prescribers retain control over the delivery process arose in the context of Defendants' argument that in-person dispensing is necessary to "prevent[] any delay in filling the prescription that may occur if mail delivery or retail pharmacies are used."

[4] *See, e.g.*, Md. Code Regs. § 10.32.23.18 (with some exceptions, requiring a special permit for clinicians to dispense medications directly to patients); Md. Code Regs. § 10.32.23.06(C)(1) (prohibiting dispensing by mail under such permit).

PI Opinion 57; *see also* Defs.' PI Opp'n 6 (citing Defs.' Ex. 14, ECF No. 62-6 ("2013 REMS Review") 0356-57). Specifically, the FDA stated in 2013 that, "[i]f this restriction was removed, any pharmacy could stock the drug and prescribers would no longer have to stock Mifeprex." 2013 REMS Review 0356. The agency asserted that a "'worst case' scenario" under those circumstances could be that "patients have difficulty finding a pharmacy that stocks the drug because not all pharmacies may choose to stock the drug, resulting in treatment delay." *Id.*

As an initial matter, Plaintiffs do not seek clarification that "any pharmacy" may stock and dispense mifepristone: it is clear that the Injunction limits dispensing to "mail or delivery services" and maintains "supervision" requirements that together preclude retail pharmacies from dispensing. *See supra* n.1. The ambiguity is not whether "any pharmacy" may now stock and dispense mifepristone under the Injunction: it is whether one or two mail-order pharmacy companies may enter into an agreement with the drug manufacturer to stock mifepristone, and then enter into agreements with clinicians who prescribe mifepristone pursuant to a REMS certification agreement to deliver the medication directly to their patients under the prescriber's supervision.

Notably, the FDA's review of Korlym identified the same concern—that retail pharmacies might not stock the medication (because of the relatively small number of Cushing's Syndrome patients)—but concluded that a distribution model in which "[p]hysicians can submit their prescriptions through this central pharmacy to have Korlym delivered directly to the patient . . . . *ensures timely access to treatment*." Korlym Summary Review 0328 (emphasis added); *see also* Korlym Medical Review 14 (distributing "Korlym solely to a 'limited number of specialty pharmacies . . . .' should prove more convenient for patients"). Of course, "[i]f in-person dispensing is the most efficient" delivery method "for a particular patient, that option will remain available." PI Opinion 57.

C. This Court Has Jurisdiction to Clarify the Scope of the Injunction.

While as a general matter, "a district court loses jurisdiction to amend or vacate its order after the notice of appeal has been filed," *Lewis v. Tobacco Workers' Int'l Union*, 577 F.2d 1135, 1139 (4th Cir. 1978), Plaintiffs' motion is well within the recognized exception to this rule that permits a district court to take limited actions that "aid[] in the appeal," which may include "clarify[ing] the bounds" of the appealed ruling. *Amaya*, 2019 WL 1501584, at *2 (citing *Dixon*, 290 F.3d at 709 n.14; other citations omitted); *see also Lytle*, 240 F.3d at 407 n.2 (permitting district court to correct "imprecise wording" as to who was subject to the injunction).

For instance, in *Dixon v. Edwards*, the Fourth Circuit found that the district court retained jurisdiction to clarify its injunction after the defendants had noticed their appeal and moved for a stay of judgment pending appeal. 290 F.3d at 709 & n.14. The post-appeal "modification order" that the Fourth Circuit endorsed contained two changes: *First*, it replaced language prohibiting the defendant from officiating religious services "on or near the grounds" of the church with language prohibiting such officiating within "300 feet" of the church. *Id.* at 709. *Second*, the post-appeal order "imposed an additional restriction, ordering that 'in conducting such services, [the defendant] shall not in any way hold himself out as being licensed by the Ecclesiastical Authority of the Episcopal Diocese of Washington.'" *Id.* This additional restriction, which the Fourth Circuit found jurisdictionally proper, covered an entirely new aspect of the matter: the original order nowhere addressed the defendant's "conduct" in officiating religious services within the vicinity of the church or the defendant's licensure, nor anywhere even referred to the "Ecclesiastical Authority of the Episcopal Diocese of Washington." *See id.*; *accord Dixon v. Edwards*, 172 F. Supp. 2d 702, 720 (D. Md. 2001).

The minor clarifications that Plaintiffs now seek in the PI Opinion—none are needed in the Injunction itself—are no more substantial than this "limited modification" of the injunctive order that the Fourth Circuit approved in *Dixon*. 290 F.3d at 709. Moreover, in remanding to the district court in *Dixon* for further consideration of one aspect of its injunction, the Fourth Circuit sought additional clarification from the district court regarding a "significant discrepancy between" the district court's order and opinion that "makes it difficult to ascertain the proper boundaries of the buffer zone where [the defendant] is not to officiate." *Id.* at 720. Here, by resolving the discrepancy between the Injunction and the PI Opinion, this Court can aid the appellate process by preempting similar confusion.

IV. CONCLUSION AND PROPOSED CLARIFICATION

Clarification is both permissible and in the interests of justice where, as here, the modification will address a discrepancy between the Court's order and its opinion, and will substantially aid both the beneficiaries of the injunction and the appellate court by eliminating an ambiguity as to the scope of the injunction. This Court has jurisdiction to make the minor adjustments Plaintiffs seek, and doing so will ensure that medication abortion patients do not continue to needlessly suffer COVID-19 risks and other burdens during the pandemic simply as a result of ambiguous language. Accordingly, Plaintiffs respectfully request the following clarifications to the PI Opinion, or whatever adjustments the Court deems appropriate:

> [W]here the REMS ~~**require that**~~ **prevents** the drug sponsor from distribut~~**e**~~**ing** mifepristone ~~**only to certified healthcare providers and not**~~ to retail pharmacies, . . . a temporary waiver of the In-Person Requirements would not open up the distribution chain in a way that takes control away from those healthcare providers. Rather, such healthcare providers would be able to choose the most efficient means of getting the drug ~~**from their office**~~ to their patient under the existing circumstances, whether by mail **(including supervised delivery from a mail-order pharmacy)**, courier, or in-person . . . .

> [D]ispensing . . . must still be conducted "by or under the supervision of a certified prescriber," and the drug sponsor must still ensure that mifepristone is not 'distributed to or dispensed through retail pharmacies,' so **~~the drug will still have to be distributed first to~~** certified healthcare providers **~~who then~~** must arrange for the mailing or delivery of the mifepristone to their patients and must still arrange to record the serial numbers of the distributed packages of mifepristone.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 5.

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